

**WE CLAIM:**

1                   1.       A method for the identification of a systemic autoimmune disease  
2 in a test subject suspected of suffering from an otherwise unidentified systemic  
3 autoimmune disease selected from the group consisting of systemic lupus erythmatosus,  
4 scleroderma, Sjögren's syndrome, polymyositis, dermatomyositis, CREST, and mixed  
5 connective tissue disease, said method comprising:

6                   (a) analyzing a single biological sample from said test subject for the  
7 presence and amounts of a plurality of autoantibodies to produce a test data set;

8                   (b) comparing said test data set to a library of reference data sets, each  
9 reference data set obtained from a biological sample of a reference subject known  
10 to have a systemic autoimmune disease of known identity; and

11                   (c) applying pattern recognition means to produce a statistically derived  
12 decision indicating which systemic autoimmune disease said test subject is  
13 suffering from.

1                   2.       A method in accordance with claim 1 in which said test subject is  
2 suffering from two systemic autoimmune diseases, and step (c) comprises applying  
3 pattern recognition means to produce a statistically derived decision indicating which two  
4 systemic autoimmune diseases said test subject is suffering from.

1                   3.       A method in accordance with claim 1 in which said pattern  
2 recognition means is a member selected from the group consisting of k-nearest neighbor  
3 analysis, multi-linear regression analysis, Bayesian probabilistic reasoning, neural  
4 network analysis, and principal component analysis.

1                   4.       A method in accordance with claim 1 in which said pattern  
2 recognition means is a k-nearest neighbor analysis.

1                   5.       A method in accordance with claim 1 in which said plurality of  
2 autoantibodies numbers from 10 to 100 autoantibodies.

1                   6.       A method in accordance with claim 1 in which said plurality of  
2 autoantibodies numbers from 15 to 25 autoantibodies.

1                   7.       A method in accordance with claim 1 in which said plurality of  
2 autoantibodies comprises antibodies to at least fifteen of the following antigens:

002407-50416960

3	SSA 60
4	SSA 60
5	SSA 52
6	SSB 48
7	Sm BB'
8	Sm D1
9	RNP 68
10	RNP A
11	RNP C
12	Fibrillarin
13	Riboproteins P0, P1, and P2
14	dsDNA
15	Nucleosome
16	Ku
17	Centromere A
18	Centromere B
19	Scl-70
20	Pm-Scl
21	RNA-Polymerases 1, 2, and 3
22	Th
23	Jo-1
24	Mi-2
25	PL7
26	PL12
27	SRP

1           8.       A method in accordance with claim 1 in which said plurality of  
2 autoantibodies comprises antibodies to each of the following antigens:

3	SSA 60
4	SSA 60
5	SSA 52
6	SSB 48
7	Sm BB'
8	Sm D1

9 RNP 68  
 10 RNP A  
 11 RNP C  
 12 Fibrillarin  
 13 Riboproteins P0, P1, and P2  
 14 dsDNA  
 15 Nucleosome  
 16 Ku  
 17 Centromere A  
 18 Centromere B  
 19 Scl-70  
 20 Pm-Scl  
 21 RNA-Polymerases 1, 2, and 3  
 22 Th  
 23 Jo-1  
 24 Mi-2  
 25 PL7  
 26 PL12  
 27 SRP

1 9. A method in accordance with claim 1 in which said library of  
 2 reference data sets represents from 100 to 10,000 biological samples from reference  
 3 subjects known to have systemic autoimmune diseases of known identity.

1 10. A method in accordance with claim 1 in which said library of  
 2 reference data sets represents from 200 to 2000 biological samples from reference  
 3 subjects known to have systemic autoimmune diseases of known identity.

1 11. A method in accordance with claim 1 in which step (c) further  
 2 comprises assigning a confidence level to said determination.

1 12. A method in accordance with claim 1 in which said biological  
 2 sample from said test subject is a member selected from the group consisting of serum,  
 3 plasma, urine, and cerebrospinal fluid.

1                   13.     A method in accordance with claim 1 in which said biological  
2     sample from said test subject is serum.

1                   14.     A method in accordance with claim 1 in which step (a) is  
2     performed by immunoassay.

1                   15.     A method in accordance with claim 1 in which step (a) is  
2     performed by immunoassay with fluorescence detection.

1                   16.     A method in accordance with claim 1 in which said systemic  
2     autoimmune disease is systemic lupus erythmatosus.

SUB  
B1

002707-50416960

add  
B1